## REMARKS

In response to the Office Action dated May 17, 2005, Applicants respectfully request that the above amendments be entered and the following remarks be considered. Claims 1-14 and 17-24 are currently pending in the application. Claims 4, 5 and 19 have been withdrawn.

**Objections**

Paragraph [0004] of the specification has been objected to for use of the incorrect patent number. Applicants have amended paragraph [0004] to reflect the correct patent number. As such, Applicants request withdrawal of the objection.

Paragraph [0015] of the specification has been objected for the recitation of "later flow" dipstick. It is asserted that it is not clear what type of dipstick is used. Applicants submit this is a typographical error and should recite "lateral flow" dipstick. Applicants have amended paragraph [0015] accordingly and submit that no new matter has been added by way of the amended as a lateral flow membrane is recited in claim 14 of the original specification. As such, Applicants request withdrawal of the objection.

**35 U.S.C. § 112, Second Paragraph, Rejections**

Claims 6, 10-11, 13-14, 20 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Particularly, the claims stand rejected as vague and indefinite in reciting "endogenous" anti-neutrophil cytoplasmic antibodies "because the point of reference(s) defining the boundary between 'endogenous' and 'nonendogenous' is not clear *Office Action*, page 3. Applicants respectfully submit that the term "endogenous" has been

removed from amended claims 6, 10-11, 13-14, 20 and 24. As such, Applicants request withdrawal of the 112 rejection of these claims.

Claims 6 and 20 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the claims were rejected for the use of the term "the total." Applicants submit that claims 6 and 20 have been amended to remove reference to "the" total. Applicants respectfully submit that the term "total" is intended to describe the complete anti-neutrophil cytoplasmic antibodies and smaller degraded forms that may occur in the gut following protease and acid digestion. Applicants submit that polyclonal antibodies bind all forms of the antibodies. See Specification, paragraph 16. As such, Applicants request withdrawal of the 112 rejection of claims 6 and 20.

Claim 13 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular the claim has been rejected for failing to provide antecedent basis for the term "the antibodies." Applicants have amended claim 13 to specify that the term "the antibodies" is referring to the anti-neutrophil cytoplasmic antibodies. As such, Applicants request withdrawal of the 112 rejection of this claim.

Claim 14 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, it is stated that it is unclear whether a Markush-type claim is intended. Applicants have amended claim 14 to more clearly show that a Markush-type claim is intended. As such, Applicants request withdrawal of the 112 rejection of claim 14.

## 35 U.S.C. § 103(a) Obviousness Rejections

Applicable Authority

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP §2143 through §2143.03. In order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)." *Id. See also* MPEP §706.02(j) and §2142.

Obviousness Rejection Based on the in view of the Walsh and Rose reference (U.S. Patent 6,218,129) in view of the Padron reference (U.S. Patent 5,359,038)

Claims 1-3, 6-14, 17-18 and 20-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. .Patent No. 6,218,129 to Walsh and Rose (the "Walsh and Rose reference) in view of U.S. Patent No. 5,359,038 to Padron (the "Padron reference"). As the

Walsh and Rose reference and the Pardron reference fails to teach or suggest all the limitations of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1 recites a method for testing a fecal sample. The method comprises obtaining a fecal sample from a person and determining whether anti-neutrophil cytoplasmic antibodies are present in the sample.

By way of contrast the Walsh and Rose reference teaches a method for diagnosing inflammatory bowel disease (IBD) by obtaining a serum sample for a patient and determining whether the sample is positive for anti-neutrophil cytoplasmic antibodies (ANCA). The Walsh and Rose reference neither teaches nor suggests determining whether ANCA are present in a fecal sample. It does not disclose that ANCA may be in the feces of humans or that ANCA can cross through the intestinal wall from the serum and be contained in feces. As such, it does not teach or disclose determining whether ANCA is present in a fecal sample.

Further, the Padron reference also does not teach nor suggest determining whether ANCA is present in a fecal sample. Rather, the Padron reference discloses isolating immunoglobulins in the feces of humans and animals. The Padron reference merely purifies large amounts of nonspecific antibodies by a chemical precipitating process. It does not disclose that ANCA is contained in the feces of humans or that ANCA can cross through the intestinal wall and be contained in feces. As such, the method disclosed by Padron is not specific enough such that the method for isolating non-specific immunoglobulins could not be used by one of skill in the art to determine that ANCA crosses the intestinal wall and may be present in feces. As such, the Padron reference also does not disclose determining whether ANCA is present in a fecal sample.

In view of the above, it is respectfully submitted that the Walsh and Rose reference in view of the Padron reference fails to teach or suggest all of the limitations of independent claim 1 and a *prima facie* case of obviousness cannot be established for the claims based upon the cited combination. *See, In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 1 is requested. Furthermore, as claims 2-3 and 6-10 depend directly or indirectly from claim 1, Applicants request withdrawal of the 103(a) rejection of these claims as well.

Independent claim 11, as amended herein, recites a diagnostic assay for diagnosing ulcerative colitis by determining anti-neutrophil cytoplasmic antibodies. The assay comprises obtaining a human fecal sample and diluting the fecal sample. The sample is contacted with neutrophil cytoplasmic antigens to create a treated sample. The treated sample is contacted with polyvalent antibodies to human immunoglobulin to create a readable sample. The optical density of the readable sample is determined at 450 nm.

By way of contrast the Walsh and Rose reference teaches a method for diagnosing inflammatory bowel disease (IBD) by obtaining a serum sample for a patient and determining whether the sample is positive for anti-neutrophil cytoplasmic antibodies (ANCA). Again, the Walsh and Rose reference neither teaches nor suggests determining whether ANCA are present in a fecal sample. It does not disclose that ANCA may be in the feces of humans or that ANCA can cross through the intestinal wall from the serum and be contained in feces. As such, it does not teach or disclose contacting a fecal sample with neutrophil cytoplasmic antigens to create a treated sample. Nor does the Walsh and Rose reference teach contacting the treated fecal sample with polyvalent antibodies to human immunoglobulin to create a readable sample and determining the optical density of the readable sample at 450 nm.

Further, the Padron reference also does not teach nor suggest determining the presence of ANCA in a fecal sample. Rather, the Padron reference discloses isolating nonspecific immunoglobulins in the feces of humans and animals. The Padron reference merely purifies large amounts of nonspecific antibodies by a chemical precipitating process. It does not disclose that ANCA is contained in the feces of humans or that ANCA can cross through the intestinal wall and be contained in feces. As such, the method disclosed by Padron is not specific enough such that the method for isolating non-specific immunoglobulins could not be used by one of skill in the art to determine that ANCA crosses the intestinal wall and may be present in feces. As such, the Padron reference also does not teach or disclose contacting a fecal sample with neutrophil cytoplasmic antigens to create a treated sample. Nor does the Padron reference teach contacting the treated fecal sample with polyvalent antibodies to human immunoglobulin to create a readable sample and determining the optical density of the readable sample at 450 nm.

In view of the above, it is submitted that the Walsh and Rose reference in view of the Padron reference fails to teach or suggest all of the limitations of independent claim 11 and a *prima facie* case of obviousness cannot be established for the claims based upon the cited combination. *See, In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 11 is requested. Furthermore, as claims 12-14 depend directly or indirectly from claim 11, Applicants request withdrawal of the 103(a) rejection of these claims as well.

Independent claim 17, as amended herein, recites a method for screening for ulcerative colitis. The method comprises obtaining a fecal sample from a person and determining whether anti-neutrophil cytoplasmic antibodies are present in the sample. If anti-neutrophil cytoplasmic antibodies are present a diagnosis of ulcerative colitis may be substantially concluded.

By way of contrast the Walsh and Rose reference teaches a method for diagnosing inflammatory bowel disease (IBD) by obtaining a serum sample for a patient and determining whether the sample is positive for anti-neutrophil cytoplasmic antibodies (ANCA). The Walsh and Rose reference neither teaches nor suggests determining whether ANCA are present in a fecal sample. It does not disclose that ANCA may be in the feces of humans or that ANCA can cross through the intestinal wall from the serum and be contained in feces. As such, it does not teach or disclose determining whether ANCA is present in a fecal sample and if so, substantially concluding a diagnosis of ulcerative colitis.

Further, the Padron reference also does not teach nor suggest determining whether ANCA is present in a fecal sample. Rather, the Padron reference discloses isolating immunoglobulins in the feces of humans and animals. The Padron reference merely purifies large amounts of nonspecific antibodies by a chemical precipitating process. It does not disclose that ANCA is contained in the feces of humans or that ANCA can cross through the intestinal wall and be contained in feces. As such, the method disclosed by Padron is not specific enough such that the method for isolating non-specific immunoglobulins could not be used by one of skill in the art to determine that ANCA crosses the intestinal wall and may be present in feces. As such, the Padron reference also does not disclose determining whether ANCA is present in a fecal sample and if so, substantially concluding a diagnosis of ulcerative colitis.

In view of the above, it is respectfully submitted that the Walsh and Rose reference in view of the Padron reference fails to teach or suggest all of the limitations of independent claim 17 thus, a *prima facie* case of obviousness cannot be established for the claims based upon the cited combination. *See, In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 17 is requested. Furthermore, as claims 18 and 20-24 depend directly or indirectly from claim 17, Applicants request withdrawal of the 103(a) rejection of these claims as well.

## CONCLUSION

Each of claims 1–6 is believed to be in condition for allowance, and a timely notice of allowance solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicant's undersigned attorney.

It is believed that no fee is due in conjunction with the present Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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